

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 09-08-87

OUT 10/14/87

Srinivas Gowda WEC 10-16-87

Reviewed By Srinivas Gowda Date 10/14/87

EPA Reg. No. or File Symbol 8383-3

EPA Petition or EUP No. None

Date Division Received 07-17-87 & 08/05/87

Type Product(s): Hospital Disinfectant

Data Accession No(s) 402830-01

Product Mgr. No. 32 (Kempter)

Product Name(s) Permacide Brand Ristex Germicidal/Disinfectant

Company Name (s) Sporicidin International

Submission Purpose Amendment to add additional brand names and
additional virucidal claim (Influenza A₂/Japan)
with data, label, and technical brochure

Chemical & Formulation Ready-to-use liquid

Active Ingredient (s): 8

Phenol.....1.41

Sodium Phenate.....0.24

Sodium Borate.....0.47

200.00 Introduction

200.1 Use (s)

Proposed labels are attached.

200.2 Background Information

The submission received 07-17-87, is an amendment to add an additional virucidal claim against Influenza A₂/Japan. A revised label and a technical brochure were also submitted.

The submission received 08-05-87, is an amendment to include the following additional brand names:

1. Sporidicin Brand Germicidal Towelette
2. Sporidicin Brand Disinfectant Towelette
3. Permicide Germicidal Towelette
4. Permicide Disinfectant Towelette
5. Rear Guard Germicidal Towelette
6. Rear Guard Disinfectant Towelette
7. Derma La Douche Germicidal Towelette
8. Derma La Douche Disinfectant Towelette
9. Vetricidin Germicidal Towelette
10. Vetricidin Disinfectant Towelette
11. O.R. Germicidal Towelette
12. O.R. Disinfectant Towelette

201.0 Data Summary

201.1 Brief Description of Test

Reports of Virucidal Tests by Herbert N. Prince and Daniel L. Prince, Gibraltar Biological Laboratories, Inc., 23 Just Road, Fairfield, New Jersey 07006, dated 06-25-87 (Accession Nos. 402830-01)

201.2 Test Summaries

a. Virucidal Tests:

1. Method: A.O.A.C. Germicidal Spray Products Test
2. Modifications: 100% Chorioallantoic fluid as organic soil (protein concentration equivalent at least to 5% calf serum).
3. Samples: 42478/1-2.

<u>Batch No.</u>	<u>Mfg.Date</u>	<u>Test Dates</u>
A	Not Listed	06-11-87 thru 06-25-87
B	"	"

4. Dilution: Spray over the virus film until wet.
5. Exposure: 10 minutes at 20-25°C
6. Recovery Medium/Neutralizer/Diluent:
Trypticase soy broth (TSB) was added to the virus-germicide mixture so as to achieve a total volume 2.0 ml and diluted in TSB to 10^{-5} .
7. Incubation : 48 hours at 35°C
8. Test Virus Host System: 13 days old chick embryo
9. Assay System for Virus Recovery: Hemagglutination Test.
10. Drying Time and Temperature: 35°C \pm 1°C for 30-45 min.
11. Method for Estimating 50 Per Cent end-point: Reed-Muench.
12. Test Virus: Influenza A₂ Japan/305/57
13. Test Results

<u>ID-50 or LD-50 (-log 10)</u>					
<u>Test Virus</u>	<u>Batch No.</u>	<u>Virus Control</u>	<u>Virus + Disinf.</u>	<u>Toxicity Control</u>	<u>Virus Inacti.</u>
Influenza A ₂ /Japan	A	6.0	0	0	6.0
	B	6.0	0	0	6.0

15. Conclusions: Satisfactory performance vs Influenza virus Type A₂/Japan/305/57 as an undiluted spray in the presence of 100% CAF (equivalent to 5% calf serum) on moderately soiled, hard, non-porous surfaces for a contact time of 10 minutes at 20-25°C.